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PRE-APPEAL BRIEF REQUEST FOR REVIEW	Docket Number (Optional) 03-044

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Application Number	Filed
10/631,871	July 31, 2003

First Named Inventor: Sharon Mi Lyn Tan

Art Unit	Examiner
1615	Carlos A. Azpuru

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant /inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 29,674
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34.

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NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[x] *Total of 1 forms are submitted.

REASONS FOR REQUESTING PRE-APPEAL REVIEW

1) Status of Claims

Claims 1-23 are pending in the application and are presented for this Pre-Appeal Review.

2) The Rejection Under 35 U.S.C. 103 Based on UMEMURA in View of TROGOLO and MCGLOTHLIN is Erroneous

Claims 1-23-are rejected under 35 U.S.C. 103(a) based on Umemura et al. (U.S. Patent No. 4,902,503) ("UMEMURA") in view of Trogolo et al (U.S. Patent Application Publication No. 2003/0118664 ("TROGOLO") and McGlothlin et al. (U.S. Patent No 6,329,444) ("MCGLOTHLIN"). This rejection is in error and should be withdrawn

The present invention is directed to medical articles that comprise an antimicrobial region, which antimicrobial region comprises release-modulating dispersed microparticles within a latex polymer. The release-modulating microparticles comprise an antimicrobial agent and are adapted to release the antimicrobial agent. In particular, Claim 1 of the present invention provides:

> 1. A medical article that comprises an antimicrobial region, said antimicrobial region comprising release-modulating microparticles dispersed within a latex polymer, said release-modulating microparticles comprising an antimicrobial agent and being adapted to release the antimicrobial agent, wherein said microparticles comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed.

In contrast to the present invention, UMEMURA teaches:

> A first antimicrobial latex composition comprising a homogeneous blend of a natural rubber latex or a synthetic polymer latex and protein silver and a second antimicrobial latex composition comprising a homogeneous blend of a cationic natural rubber latex or a cationic synthetic polymer latex and a water-soluble silver compound, wherein each antimicrobial latex composition exhibits excellent long term stability during storage and can be readily prepared. (See Abstract) (emphasis added)

In addition to the fact that the non-comparative Examples 1-7 in UMERURA use dissolved protein silver, UMEMURA clearly describes its antimicrobial latex compositions as containing dissolved silver:

> This antimicrobial latex composition may be prepared by virtually any known method as in the case of the protein silver. For example, an aqueous solution of a water-soluble silver compound, particularly that having a high concentration of the water-soluble silver compound, may be directly added to a latex. (col.5, lines 20-25) (emphasis added)

More particularly, UMEMURA discloses two types of antimicrobial latex compositions.

1) The first type contains a homogeneous blend of a natural rubber latex or a synthetic polymer latex and protein silver. This first type utilizes a latex, e.g., natural rubber latex, and a silver protein complex, protein-silver, dissolved in the aqueous phase of the latexes. It is important to note that this first type of antimicrobial latex composition requires the silver to be water soluble. (See the Abstract; and specification at col. 2, line 60; col. 4, lines 45-48; col. 4, lines 54-57; and col. 5, lines 54-56.)

In contrast to the present invention, this first type of antimicrobial latex composition from UMEMURA does not describe a medical article comprising "release-modulating microparticles dispersed within a latex polymer" as claimed in Claim 1, much less one "wherein said microparticles comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed".

2) The second type uses a homogeneous blend of a cationic natural or synthetic rubber and soluble silver compounds, e.g., silver nitrate, among others. (See, e.g., Abstract; and specification at col. 4, lines 49-53.) As with the protein silver, the water-soluble silver compounds are dissolved in the aqueous phase. (See, e.g., col. 8, lines 41-42.)

As noted above for the first type of antimicrobial latex composition, the second type of antimicrobial latex composition in UMEMURA lacks any teaching of several of the key components of the invention: "release-modulating microparticles disposed within a latex polymer," and "microparticles [that] comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed" as claimed.

In the Advisory Action, the Examiner states that UMEMURA is not being used for its teaching on microparticles, but rather for the point that "latex with silver within it is known as taught by [UMEMURA]". The Examiner has previously taken the position that the term "latex" as used by Applicant is far broader than the literal definition and encompasses the polymers of UMEMURA. This view, however, is irrelevant to the claimed invention. It must be noted that regardless of the definition of "latex", UMEMURA still lacks the elements of "release-modulating microparticles disposed within a latex polymer," and "microparticles [that] comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed" as claimed.

Additionally, Applicant wishes to point out that UMEMURA (col. 2, lines 18-31) recites that a latex, such as a natural rubber latex dispersed in water, is a highly unstable system. Consequently, when an aqueous solution containing a highly soluble silver compound is added to a latex at a high concentration in order to give a high silver concentration in the resulting matrix material, the silver nitrate has been observed to break the system. Moreover, when silver carbonate, which has an extremely low solubility in water, is added, the stable latex dispersion system is also broken and aggregation is observed. Therefore, it has been impossible to obtain a stable latex composition.

UMEMURA attempts to solve this stability problem by its technique as described at col. 2, lines 62-68:

> Accordingly, the crux of the present invention resides in an antimicrobial latex composition prepared by blending silver protein with a natural rubber latex or a synthetic polymer latex, and in an antimicrobial latex composition prepared by blending water-soluble silver compound with a cationic natural rubber latex or a cationic synthetic polymer latex.

Because UMEMURA teaches the use of silver protein and other water soluble silver compounds in its invention, UMEMURA clearly teaches away from water-insoluble forms of antimicrobial latex (i.e., release-modulating microparticles comprising an antimicrobial agent) like that claimed. See MPEP 2141.02.VI ("Prior Art Must Be Considered In Its Entirety, Including Disclosures That Teach Away From The Claims"). Moreover, even assuming for the sake of argument that one were to substitute a water-insoluble form as proposed by the Examiner, there would be no expectation of success. See MPEP 2143.02 ("Reasonable Expectation of Success is Required.")

TROGOLO is added in an attempt to overcome the deficiencies in UMEMURA. In the Advisory Action, the Examiner repeats his point that TROGOLO "teaches that antibiotics may be encapsulated". TROGOLO explains that the "microcapsule comprising an inorganic antimicrobial agent" is "coated with a hydrophilic polymer." See Abstract. TROGOLO also teaches the incorporation of antimicrobial microcapsules into a polymer matrix. See paragraph 68.

TROGOLO, however, does not teach or suggest that the antimicrobial microcapsules can be deposed in a latex polymer. In fact, TROGOLO does not appear to disclose any type of latex whatsoever. Contrary to the Examiner's position, the polymers of TROGOLO do not include the term "latex" even as it is used by Applicant. As defined in paragraph [0021] of the current specification, a "latex," is "an aqueous polymer dispersion." By "aqueous polymer dispersion" is meant "a dispersion of polymer particles in a water-containing fluid." As indicated in a previous

Office Action, the term "latex" as defined by Applicant is not restricted to a particular polymer; however, it does require "a dispersion of polymer particles in a water-containing fluid." Nothing of the sort is taught by TROGOLO.

TROGOLO actually teaches away from using latexes at paragraph [0081], where the advantages of thermal/melt processing are disclosed, which advantages may be considered unique to the process disclosed and essential to the enhanced antimicrobial functioning of the resulting articles. See, e.g., MPEP 2141.02 VI and the cases cited therein.

Thus, there is no reason that one skilled in the art would combine the antimicrobial microcapsules of TROGOLO with UMEMURA, especially since UMEMURA actually teaches away from such antimicrobial microcapsules by requiring the use of soluble antimicrobial agents in order to avoid latex instability. See MPEP 2141.02.VI.

The rejection based on TROGOLO with UMEMURA relies on the combination of two references each of which does not teach the elements of the claimed invention and which, by reason of their individual subject matter are not combinable. Thus, at the very least, the combination would have been unwarranted by the disclosures in the references. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q 1125 (Fed. Cir. 1984), *Carl Schenk, A.G. v. Norton Corporation*, 713 F.2d 782, 218 U.S.P.Q. 698, 702 (Fed. Cir. 1983), *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959), MPEP 2143.01, last paragraph. Consequently, the rejection could only have been based on undue hindsight reconstruction of the references. MPEP 2142, second paragraph, *Akzo N.V. v. U.S. International Trade Commission*, 808 F.2d 1241, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied,* 482 U.S. 909 (1987), *Loctite Corp. v. Ultraseal Ltd.,* 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985).

Moreover, even if the references were combined, there would not be a reasonable expectation of success. For example, one of ordinary skill would not reasonably expect success in using the antimicrobial microcapsules of TROGOLO in the latex-based process of UMEMURA, because UMEMURA requires the use of a dissolved antimicrobial agent in order to avoid latex instability. Again, the combination of the teachings of UMEMURA and TROGOLO is directly contrary to what one of ordinary skill would have done with any expectation of success. See MPEP 2143.02 and the cases cited therein.

The addition of MCGLOTHLIN to the combination of UMEMURA and TROGOLO likewise fails. MCGLOTHLIN describes:

> Medical devices of synthetic rubber are prepared from cis-1,4-polyisoprene by dip molding without the use of sulfur containing components. The devices have surprisingly favorable

> tensile characteristics . . . [and are] freely usable without causing the user to suffer Type I or Type IV allergic reactions that typically arise from contact with natural rubber. (See Abstract)

MCGLOTHLIN also teaches medical devices of synthetic rubber prepared from cis-1,4-polyisoprene by dip molding without the use of sulfur containing components.

The relevance of MCGLOTHLIN, if any, to the current invention is remote. In the Advisory Action the Examiner again notes that MCGLOTHLIN has been relied on as merely showing that coating of medical devices through dip molding is established (such as using one of the polymers defined as a latex). There is no teaching in MCGLOTHLIN, however, pertaining to antimicrobials, either soluble or as microparticles. Like UMEMURA and TROGOLO there is nothing in MCGLOTHLIN that teaches or suggests "release-modulating microparticles disposed within a latex polymer," and, even more particularly, of "microparticles [that] comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed" as claimed. Thus, MCGLOTHLIN adds nothing relevant to the combination of UMEMURA and TROGOLO discussed above, especially since it contains no teachings whatsoever pertaining to antimicrobials, much less "microparticles [that] comprise a core and an encapsulating layer surrounding said core or wherein the microparticles comprise a material within which the antimicrobial compound is dispersed".

Thus, the combination of UMEMURA, TROGOLO and MCGLOTHLIN fails to give the currently claimed invention with each and every limitation as described in the claims.

Thus, the rejection under 35 U.S.C § 103(a) is in error and should be reversed.

-For at least these reasons, Applicant respectfully submits that Claims 1-23 are patentable over the cited references and the rejection should be withdrawn.